CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:NDA 20738/S001

CORRESPONDENCE

K. Bongiovanni

AUG 21 1998

NDA 20-738/S-001

SmithKline Beecham Pharmaceuticals
Attention: Ms. Linda Rebar
1250 South Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

Dear Ms. Rebar:

Please refer to your new drug application (NDA) for Teveten (eprosartan mesylate) 300 and 400 mg Tablets.

In reviewing your submission of January 26, 1998, our Medical Officer and Statistician have raised a number of questions that require your attention. Our concerns with your submission are detailed as part of this correspondence (see enclosure).

Sincerely yours,

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure
NStockbridge/WNuri Med/Stat Review 6/24/98

cc:
Original
HFD-110
HFD-110/KBongiovanni
sb/8/14/98

GENERAL CORRESPONDENCE

D. Willard

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-738/S-001

FEB 3 - 1998

SmithKline Beecham Pharmaceuticals
1250 South Collegeville Rd ., UP 4455
P.O. Box 5089
Collegeville, PA 19426-0989

Attention: Linda Rebar
Manager
U.S. Regulatory Affairs

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Teveten (eprosartan mesylate) Tablets

NDA Number: 20-738

Supplement Number: S-001

Date of Supplement: January 26, 1998

Date of Receipt: January 26, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on March 27, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Cardio-Renal Products, HFD-110
Office of Drug Evaluation I
Attention: Document Control Room 5002
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/S/

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Products, HFD-110
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA 20-738/001
HFD-110/Div. Files
HFD-110/CSO/Diana, Willadard, D.W. 2/3/98

filename: C:\WPWIN61\TEMPLATE\FDA\20738S01.WPD

SUPPLEMENT ACKNOWLEDGEMENT 13.C.C. 1-27-98

2/3/98

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AUG 21 1998

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